

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

THIS PAGE BLANK (USPTO)



0400-0
PATENT #3.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: ALMOND et al.

Attorney Docket No.: UD&LP063

Application No.: 09/866,461

Examiner: Unassigned

Filed: May 24, 2001

Group: Unknown

Title: SURGICAL SEAL

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail to: Commissioner for Patents, Washington, DC 20231 on July 18, 2001.

Signed: _____

Sandra Halliwell

TRANSMITTAL OF CERTIFIED PRIORITY DOCUMENTS

Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith is the certified copy of the priority document for the above-referenced patent application, Great Britain Patent Application No. 0012461.0.

The Commissioner is authorized to charge any fees that may be due to Deposit Account No. 500388 (Order No. UD&LP063).

Respectfully submitted,

BEYER WEAVER & THOMAS, LLP

Steve D Beyer
Registration No. 31,234

P.O. Box 778
Berkeley, CA 94704-0778
(650) 961-8300

THIS PAGE BLANK (USPTO)



INVESTOR IN PEOPLE

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

[Faint, illegible text]

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

R. Mahoney

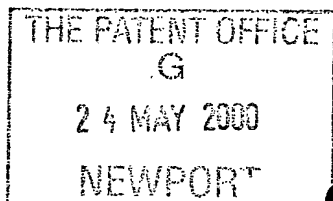
Dated

04 JUN 2001

THIS PAGE BLANK (USPTO)

Official use

24MAY00 E539265-5 D02835
P01/7700 0.00-0012461.0



Your reference
RFB/P60244

0012461.0

24 MAY 2000

Notes

Please type, or write in dark ink using CAPITAL letters. A prescribed fee is payable for a request for grant of a patent. For details, please contact the Patent Office (telephone 071-438 4700).

Rule 16 of the Patents Rules 1990 is the main rule governing the completion and filing of this form.

2 Do not give trading styles, for example, 'Trading as XYZ company', nationality or former names, for example, 'formerly (known as) ABC Ltd' as these are not required.

Warning

After an application for a Patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977 and will inform the applicant if such prohibition or restriction is necessary. Applicants resident in the United Kingdom are also reminded that under Section 23, applications may not be filed abroad without written permission unless an application has been filed not less than 6 weeks previously in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction revoked.

The
Patent
Office

Request for grant of a Patent Form 1/77

Patents Act 1977

1 Title of invention

SURGICAL SEAL

1 Please give the title of the invention

2 Applicant's details

☐ First or only applicant

2a If you are applying as a corporate body please give:

Corporate name
SURGICAL INNOVATIONS LTD

Country (and State of incorporation, if appropriate)

2b If you are applying as an individual or one of a partnership please give in full:

Surname

Forenames

2c In all cases, please give the following details:

Address
CLAYTON PARK
CLAYTON WOOD RISE
LEEDS

UK postcode LS16 6RF
(if applicable)

Country GB

ADP number (if known) 641106.0002

2d, 2e and 2f:
If there are further applicants
please provide details on a separate
sheet of paper.

☐ **Second applicant (if any)**

2d If you are applying as a corporate body please give:

Corporate name

Country (and State of incorporation, if appropriate)

2e If you are applying as an individual or one of a partnership please give in full:

Surname

Forenames

2f In all cases, please give the following details:

Address

UK postcode
(if applicable)

Country

ADP number
(if known)

3
An address for service in the United
Kingdom must be supplied.

Please mark correct box

3. Address for service details

3a Have you appointed an agent to deal with your application?

Yes ☒ No ☐ ➡ go to 3b

↓
Please give details below

Agent's name

URQUHART-DYKES & LORD

Agent's address

TOWER HOUSE

MERRION WAY

LEEDS

WEST YORKSHIRE

Postcode LS2 8PA

Agent's ADP number 1644004²³

3b:
If you have appointed an agent,
all correspondence concerning
your application will be sent to
the agent's United Kingdom
address.

3b If you have not appointed an agent please give a name and address in the United Kingdom to which all correspondence will be sent:

Name

Address

Postcode
ADP number
(if known)

Daytime telephone
number (if available)

4 Reference number

4 Agent's or applicant's
reference number
(if applicable) RFB/P60244

5 Claiming an earlier application dat

5 Are you claiming that this application be treated as having been filed on the date of filing of an earlier application?

Yes ☐ No ☒ **go to 6**

↓
please give details below

☐ number of earlier
application or patent
number

☐ filing date
(day month year)

☐ and the Section of the Patents Act 1977 under which you are claiming:

15(4) (Divisional) ☐ 8(3) ☐ 12(6) ☐ 37(4) ☐

6 Declaration of priority

6 If you are declaring priority from previous application(s), please give:

Country of filing	Priority application number (if known)	Filing date (day,month,year)
-------------------	---	---------------------------------

6

If you are declaring priority from a PCT Application please enter 'PCT' as the country and enter the country code (for example, GB) as part of the application number.

Please give the date in all number format, for example, 31/05/90 for 31 May 1990.

7

The answer must be 'No' if:
 - any applicant is not an inventor
 - there is an inventor who is not an applicant, or
 - any applicant is a corporate body.

8

Please supply duplicates of claim(s), abstract, description and drawing(s).

Please mark correct box(es)

9

You or your appointed agent (see Rule 90 of the Patents Rules 1990) must sign this request.

Please sign here ➡

A completed fee sheet should preferably accompany the fee.

7 Inventorship

7 Are you (the applicant or applicants) the sole inventor or the joint inventors?

Please mark the correct box

Yes ☐ No ☒ ➡

A statement of Inventorship on Patents Form 7/77 will need to be filed (see Rule 15).

8 Checklist

8a Please fill in the number of sheets for each of the following types of document contained in this application.

Continuation sheets for this Patents Form 1/77

Claim(s)

Description

4

Abstract

Drawing(s)

343/19

8b Which of the following documents also accompanies the application?

Priority documents (please state how many)

Translation(s) of Priority documents (please state how many)

Patents Form 7/77 - Statement of Inventorship and Right to Grant (please state how many)

Patents Form 9/77 - Preliminary Examination/Search

Patents Form 10/77 - Request for Substantive Examination

9 Request

I/We request the grant of a patent on the basis of this application.

Wright & Dykes & Lord

Signed

Date 23/05/2000

(day month year)

Please return the completed form, attachments and duplicates where requested, together with the prescribed fee to:

☐ The Comptroller
 The Patent Office
 Cardiff Road
 NEWPORT
 Gwent
 NP9 1RH

The Comptroller
 The Patent Office
 25 Southampton Buildings
 London
 WC2A 1AY

SURGICAL SEAL

This invention relates to a seal for use with a surgical instrument to provide a gas tight seal through which the instrument may pass. The invention relates particularly but not exclusively to a seal for a laparoscopic port.

Laparoscopic procedures are performed through a small incision, usually through narrow endoscopic tubes or cannulars inserted through a small entrance incision in the skin. An instrument inserted into the body must be sealed to ensure that gases do not enter or exit through the incision, for example in procedures in which the surgical region is insufflated. The introduction of a tube into an anatomical cavity such as the abdominal cavity is usually achieved using a trocar and cannular assembly. The cannular assembly may comprise a cannular attached to a cannular housing which generally includes a valve assembly adapted to maintain a seal across the opening of the valve assembly both with and without an instrument inserted through it. Various valve systems for cannular assemblies have been proposed, for example in US 5209737, US 5308336, US 5385553 and US 5545142. US 5603702 discloses a complex structure with several hinged guard members disposed in an overlapping petal-like arrangement. US 5407433 and US 5411483 disclose universal seals for laparoscopic ports. However these suffer from the disadvantage that the entire seal can move in an orbital manner. This can cause failure of the seal between the gasket and instrument during surgery.

Furthermore the friction between the annular gasket of US 5411483 and the shaft of the instrument depends on the diameter of the shaft. High frictional forces are undesirable because they impede free movement of the instrument during surgery.

According to the present invention a seal for a laparoscopic port comprises:

- a base adapted to engage a cannular, the base including an axial aperture for a surgical instrument;

- a multiplicity of jaws mounted on the base, the jaws being moveable radially with respect to the aperture between an open position wherein a shaft of the surgical instrument may pass freely and a closed position wherein the jaws engage said shaft and provide a restraining force restraining radial movement of the shaft; and

actuator rotatable to urge the jaws to move between said open position and said closed position.

In preferred embodiments the jaws may engage or restrain shafts having different diameters. In this way a single seal may be used with several instruments. In particularly preferred embodiments the jaws may be adjusted to engage a shaft having any diameter between preselected upper and lower limits.

The jaws are preferably moveable along guides provided on the carrier plate. The guides may constitute channels between raised formations, tracks or runners. Each jaw preferably comprises a follower member adapted to be received in a respective guide way in the actuator arranged so that rotation of the actuator causes radial movement of the jaw.

In a particularly preferred embodiment of the invention each guide way comprises an archuate channel formed in the actuator, a projection or other follower being received in the channel.

The channels may have the configuration of parabolic curves.

The seal of this invention may include a diaphragm adapted to contact the shaft of a surgical instrument extending through the aperture. The diaphragm preferably includes a lip, each jaw including a radially outwardly facing portion adapted to engage the lip so that the aperture in the diaphragm is forced to open as the jaws move to the open position.

The aperture of the jaws is preferably continuously adjustable between maximum and minimum positions. This allows the seal to accommodate various sizes of instrument shafts. A further advantage is that the jaws may be opened to facilitate removal of tissue samples during a surgical procedure.

The actuator may be arranged so that the jaws may be fully opened or closed by a rotation through an angle of 30 to 180°. This makes it easy for a surgeon to open or close the jaws using his fingers but without rotation of the wrist.

A top cover may be placed over the actuator to prevent occlusion of the moving parts and ingress of dirt during use.

Any convenient number of jaws may be provided, preferably 5 or more, more preferably 6 to 8.

The invention is further described by means of example but not in any limitative sense with reference to the accompanying drawings of which:

Figure 1 is an exploded view of a seal in accordance with the invention.

Figure 2 represents three plan views of the seal.

Figure 3 represents three plan views of the seal illustrating closing of the jaws.

The seal illustrated in the Figures comprises a base 1 having a locking device 2 adapted to facilitate *** attachment to a cannular. In an alternative embodiment of the invention the base 1 may be integral with a cannular.

A diaphragm or gasket 3 composed of elastomeric material lies within the base 1. The diaphragm includes an inner surface 4 adapted to receive the base of a carrier plate 18. An annular lip 5 is adapted to receive and form a gas tight seal with the shaft of an instrument (not shown). The inwardly facing surface 16 of a flange 17 extends axially from the diaphragm adjacent the rim 5. Outward movement of the flange 17 opens the aperture defined by the rim 5.

The carrier plate 18 includes a multiplicity of guideways 9 formed by axially extending runners 9. A moveable jaw member 6 can move radially within each guide way 9 in use. In the illustrated embodiment there are six jaws. Each jaw contains a radially inwardly facing tooth 16 and radially outwardly facing hook portion 7. The hook portion 7 engages the surface 16 of the diaphragm flange 17. The tooth portion 16 of each jaw serves to engage the shaft of a surgical instrument passing through the seal. A lug 8 extending axially from the upper surface of the jaw as shown is received in a channel 14 of the upper surface 13 of the actuator 12. The actuator has a generally cylindrical outer surface which may be rotated manually by a surgeon in use. The channels 14 each have a parabolic curved configuration and are spaced equidistantly around the upper surface 13 of the actuator. The configuration of the channels 14 may have the general form of an iris. Rotation of the actuator 12 causes the lugs and consequently the jaws to move radially inwardly or outwardly relative to the carrier 18. Accordingly the teeth 16 of the jaws 6 may move into and out of engagement with a shaft (not shown) extending through the aperture 15 of the seal. During opening of the jaws, the hooked portion 7 dilate the lip 5 of the gasket so that a generally even frictional force is encountered irrespective of the diameter of the shaft.

Figures 2a, b and c show the seal with the jaws in different positions. The same reference numerals are used to denote like components in Figures 1, 2 and 3.

In Figure 2a the jaws are open with the teeth 16 retracted. When the seal is engaged to a cannular, rotation of the actuator 12 in a clockwise direction causes the lugs 8 and consequently the jaws to move radially inwardly as shown in Figure 2b.

Figure 2c is a partially cut away view illustrating the jaws in the closed position.

The relative positions of the lugs 8 in the channels 14 are shown in Figures 3a, b and c. In Figure 3c the lugs are at the inner-most ends of the channels 14 so that the jaws are closed to the maximum extent. Rotation of the actuator 12 shown in Figure 3c in an anti-clockwise direction causes the jaws to move radially outwardly. Full opening of the jaws is achieved by rotation of the actuator through about 60°.

The curvature of the channels 14 is selected so that outward pressure on a jaw by lateral movement of the shaft of the surgical instrument is sufficient to overcome frictional forces within the seal. Accordingly lateral movement of the shaft cannot open the jaws. The shaft is securely held and cannot move in an orbital motion to break the seal with the gasket lip 5. Similarly a larger diameter shaft which engages the jaws in Figure 3b is also securely held. However the jaws may be easily opened by a surgeon to facilitate removal of the instrument, for example with a tissue sample of a larger diameter than the shaft.

~~The seal of this invention may incorporate a top cover, for example formed from~~
transparent waterproof material to prevent ingress of dirt or physiological material between the moving surfaces of the seal.

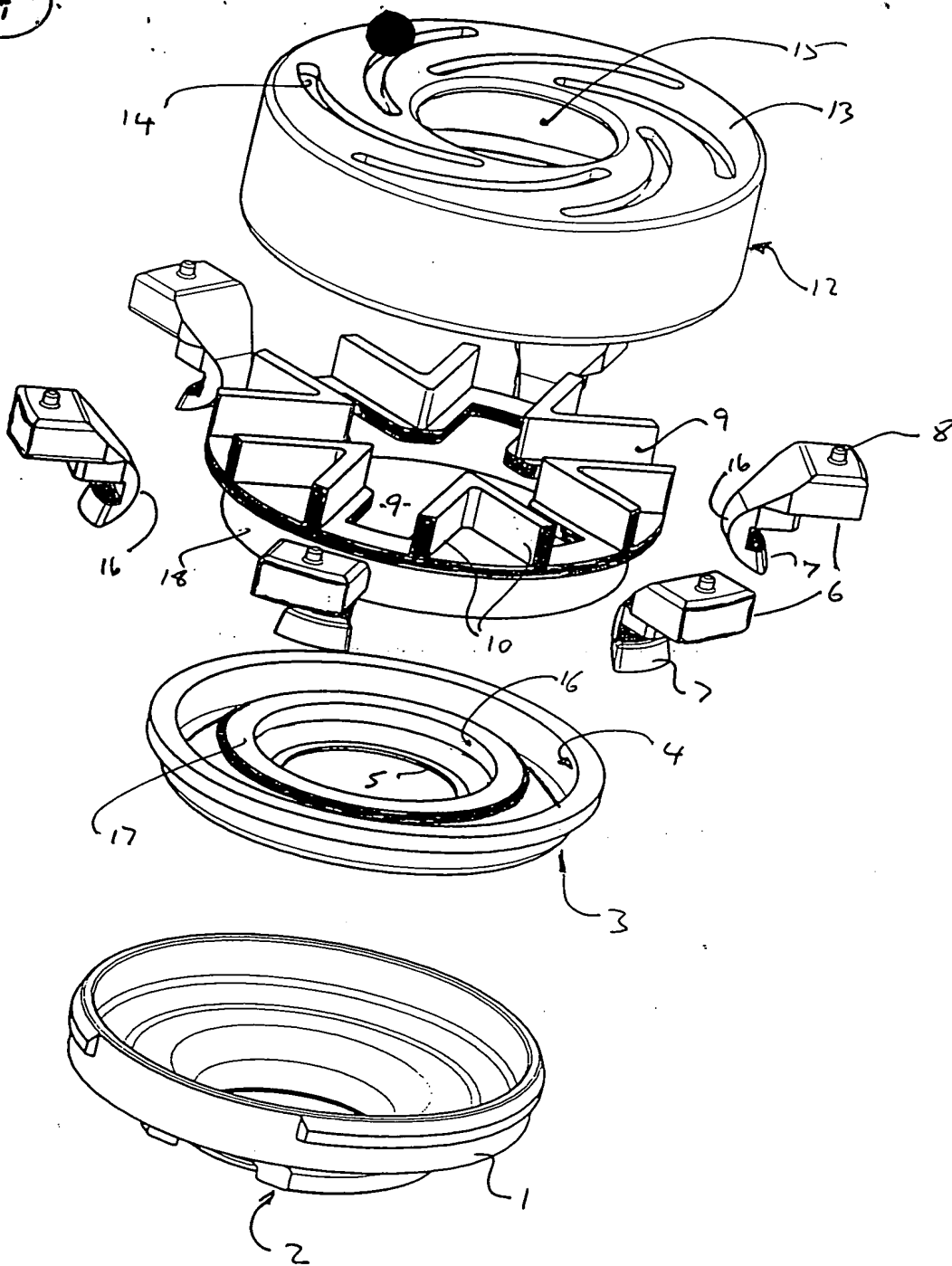


Fig 1

THIS PAGE BLANK (USPTO)

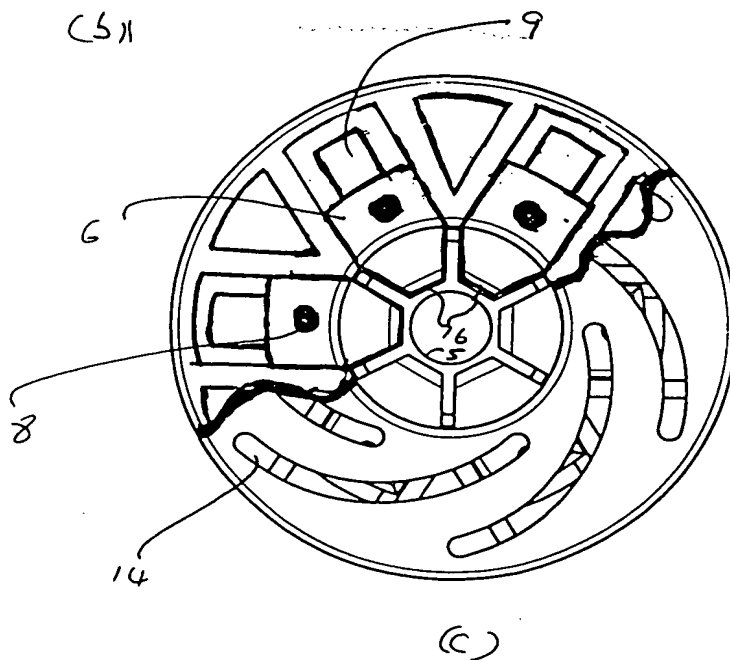
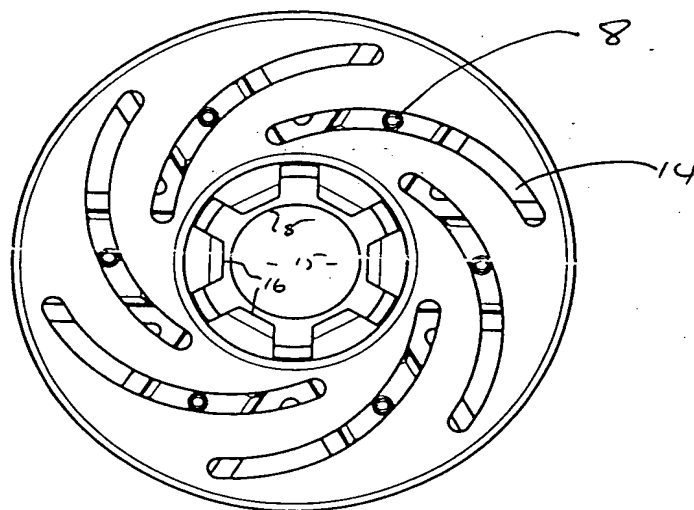
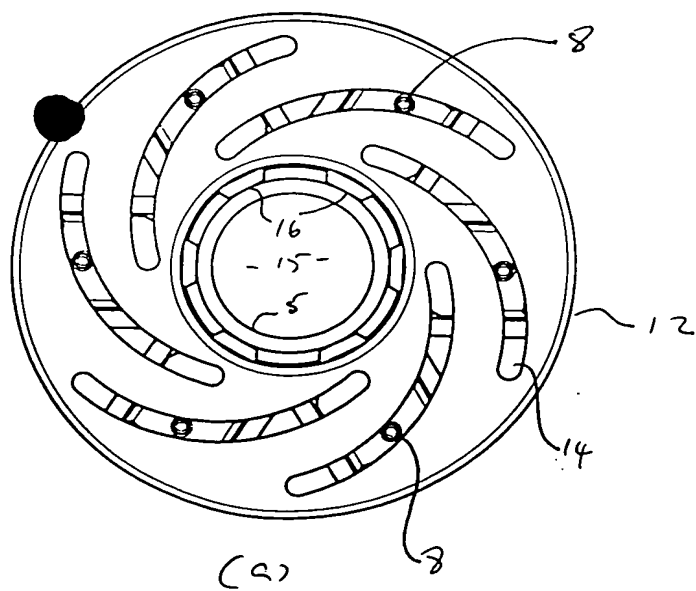


Fig 2

THIS PAGE BLANK (USPTO)

2

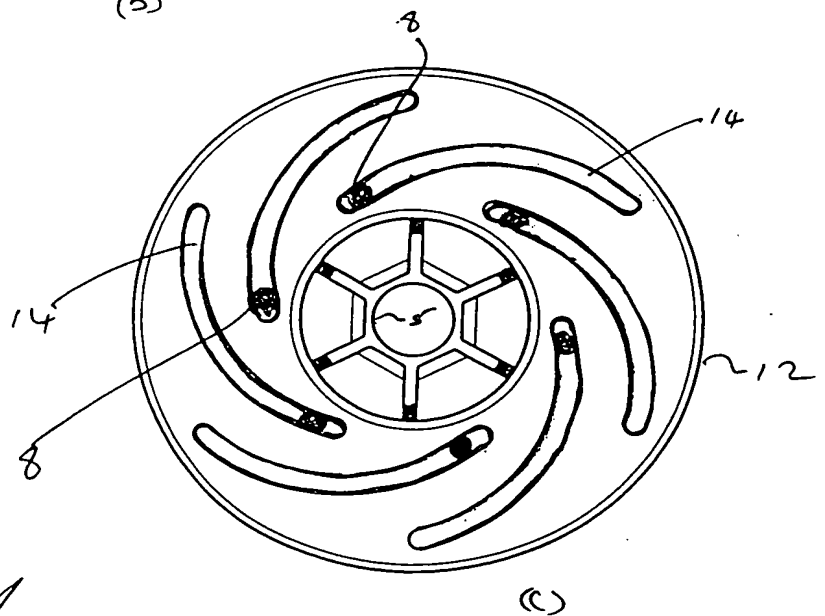
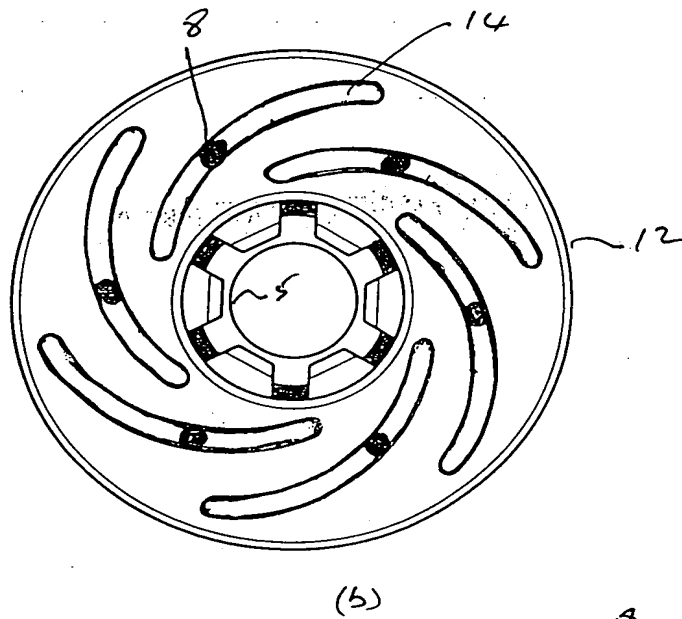
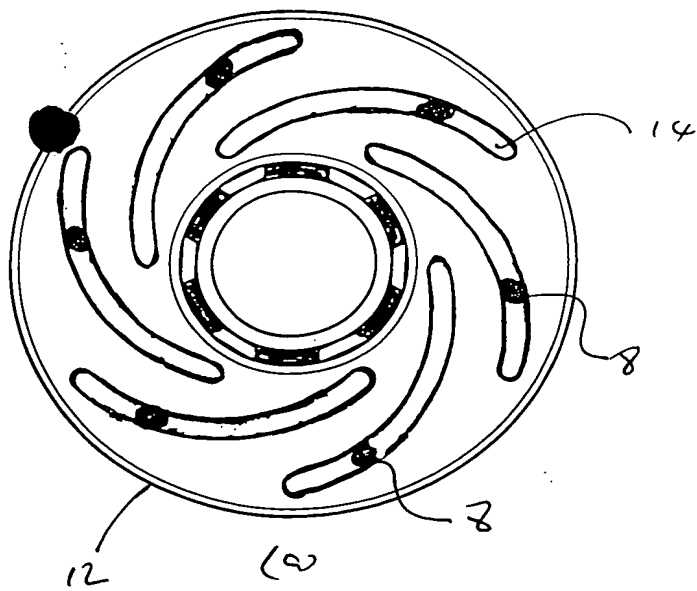


FIG 3

P. Moran 26-11-99 (c)

THIS PAGE BLANK (USPTO)